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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,801	03/11/1999	BO NIKLASSON	REF/29713/NI	2230

7590 12/10/2003

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NEW YORK, NY 10020

EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/147,801

Applicant(s)

NIKlasson, BO

Examiner

Donna C. Wortman, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 10 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: Please see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 4, 7, 9, 11 and 15-18.

Claim(s) withdrawn from consideration: 1-3, 5.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
Donna C. Wortman, Ph.D.  
Primary Examiner  
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Applicant's proposed amendment after final will not be entered since entry would raise new issues that would require further consideration and/or search and would raise the issue of new matter. Further, entry would not reduce or simplify the issues for appeal. While amending claims 4 and 16 to recite "identical to" instead of "homologous to" would overcome the rejection under 35 USC 112, second paragraph, as previously set forth, the amendment would raise new issues that would require further consideration and search since the scope of the claims would be changed. Moreover, while Applicant has pointed to the specification at page 11, Table 2; page 13, Table 3; page 10, lines 16-19; and page 11, line 46-page 12, line 15 as providing support for "identical to," no support could be located for the proposed new limitation "at least 75% identical to the amino acid sequence of SEQ ID NO:4" of claim 4 nor for "a nucleotide sequence ... at least 75% identical to SEQ ID NO:1" of claim 16, raising the issue of new matter.

With respect to the rejection of claims 4, 7, 9, 11, and 15-18 under 35 USC 112, first paragraph, as set forth in the previous Office action at page 4, as not being enabled for antigenic fragments of the amino acid sequence of SEQ ID NO:4, Applicant has argued that partial nucleotide and protein sequences are disclosed for three Ljungan virus isolates and that, as the instant specification describes, one of ordinary skill in the art would know how to determine whether a sequence is at least 75% identical with the sequences given using routine skills, and one could determine whether a protein was an antigenic fragment of either the disclosed protein, or an antigenic fragment of a protein at least 75% identical to the disclosed protein without undue experimentation, and

makes reference to Janeway and Travers, Immunobiology, pp. 1-52, attached as Exhibit A, as teaching how to determine antibody-antigen binding.

These arguments have been considered but not found persuasive. Applicant has provided a nucleotide sequence, an amino acid sequence that represents a putative protein encoded by the nucleotide sequence, but does not identify any antigenic fragment of any viral protein. The only antibody binding that is demonstrated is by an immunofluorescence test involving infected cells and antisera and does not involve the claimed protein. Since the virus is new and has not been characterized in detail, i.e., taking into account the state of the art with respect to Ljungan virus and the amount of guidance presented by Applicant with respect to that virus, it is maintained that it would require undue experimentation for one of skill in the art to practice the invention throughout the claimed scope. The Exhibit has not been considered in detail, since there is no reason it could not have been earlier presented in addressing an issue which was not raised for the first time in the final rejection. Further, insofar as Applicant's arguments rely on material in the unentered amendment, they are not persuasive as they rely on limitations not presently found in the claims.

With respect to the rejection of record of claims 15, 18, 9, 11, and 16 under 35 USC 112, first paragraph, it is first noted that the inclusion of previously canceled claim 19 in the rejection was an inadvertent error. With respect to the rejection, Applicant has reviewed the standards for "correlation" and a disclosed or claimed method of use, has pointed out that the instant specification teaches three different Ljungan viral isolates that exhibit CPE and react with a panel of human sera isolated from human

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patients with various conditions using an immunofluorescence test, that the virus sequences are similar to known cardiovirus sequences, and that the viral isolates kill suckling mice when administered intracerebrally. Applicant asserts that the evidence as a whole provides reasonable correlation between *in vitro* and *in vivo* activity. Applicant argues that one of skill in the art would know how to develop a vaccine or pharmaceutical preparation based on a protein according to claim 4 without undue experimentation, based on the determination of antigenic fragments as claimed.

These arguments have been considered but not found persuasive with respect to any pharmaceutical or vaccine applications of the claimed protein or antigenic fragments. As applicant has pointed out, if one in the art recognizes a particular model as correlating to a particular condition, then it may be accepted as correlating. However, the record provides no recognized basis for correlating Applicant's particular model, i.e., the cross-reaction of Ljungan virus-infected cells with human sera panels from patients with a variety of conditions not necessarily recognized as caused by picornaviruses, and the treatment of a particular condition, i.e., the pharmaceutical use of Ljungan viral protein or fragments of viral protein for any condition. Further, no basis for correlating intracerebral administration of virus to suckling mice with any actual disease or any pharmaceutical use of viral protein or fragments of viral protein has been established.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is

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703-308-1032 until 08 January 2004 and 571-272-0913. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until 26 January 2004 and 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'D. Wortman', with a stylized flourish at the end.

Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw